

6858/ 1679 '00 JAN-4 P2 NOT

December 15, 1999



The Office of Special Nutritionals (HFS-450) Center for Food Safety and Applied Nutrition Food and Drug Administration 200 C. Street S.W. Washington, DC 20204

Dear Sir/Madam:

This is a notification pursuant to 21 U.S.C. 343(r)(6) that Standard Process Inc., Palmyra, Wisconsin 53156-0904, is making the following statements:

- (1) Supports ovarian function.
- (2) Promotes healthy thyroid function.
- (3) By providing the building blocks necessary for proper thyroid gland function, Symplex F supports the thyroid glands' ability to maximizes the potential of all food types for energy production and increases the rate of protein synthesis in most tissues.
- (4) Enhances endocrine performance.
- (5) Maintains a healthy functional relationship between these important organs and glands.
- (6) Combines the Protomorphogen[™] extracts of bovine ovary, adrenal, pituitary, and thyroid glands to promote proper metabolism and healthy production of the female hormones.
- (7) Symplex F provides nutritional ingredients and support for the female hormones.

These statements are made for a dietary supplement containing a proprietary blend of magnesium citrate, bovine ovary PMGTM extract, bovine adrenal PMGTM extract, bovine pituitary PMGTM extract, bovine thyroid PMGTM extract (processed to remove its thyroxine). Other ingredients include calcium lactate, cellulose, and calcium stearate. The name of the product is Symplex® F.

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The information contained herein is accurate and Standard Process Inc. has substantiation that the statements are truthful and not misleading.

Sincerely yours,

Ann Holden

Standard Process Inc.

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